(a) Is dissatisfied with a carrier's denial of a request for payment made on his or her behalf by an ASC;

(b) Is dissatisfied with the amount of payment; or

(c) Believes the request for payment is not being acted upon with reasonable promptness.

Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

SOURCE: 64 FR 32205, June 16, 1999, unless otherwise noted.

§ 416.180 Definitions.

As used in this subpart, the following definitions apply:

Class of new technology intraocular lenses (IOLs) means all of the IOLs, collectively, that HCFA determines meet the definition of ''new technology IOL'' under the provisions of this subpart.

Interested party means any individual, partnership, corporation, association, society, scientific or academic establishment, professional or trade organization, or any other legal entity.

New technology IOL means an IOL that HCFA determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

New technology subset means a group of IOLs that HCFA determines meet the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs.For example, all new technology IOLs that are made of a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another.

§ 416.185 Payment review process.

(a) HCFA publishes a FEDERAL REGISTER notice announcing the deadline and requirements for submitting a request for HCFA to review payment for an IOL.

(b) HCFA receives a request to review the appropriateness of the payment amount for an IOL.

(c) HCFA compiles a list of the requests it receives and identifies the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(d) HCFA publishes the list of requests in a FEDERAL REGISTER notice with comment period, giving the public 30 days to comment on the IOLs for which review was requested.

(e) HCFA reviews the information submitted with the request to review, any timely public comments that are submitted regarding the list of IOLs published in the FEDERAL REGISTER, and any other timely information that HCFA deems relevant to decide whether to provide a payment adjustment as specified in § 416.200. HCFA makes a determination of whether the IOL meets the definition of a new technology IOL in § 416.180.

(f) If HCFA determines that a lens is a new technology IOL, HCFA establishes a payment adjustment as follows:

(1) Before July 16, 2002—$50.

(2) After July 16, 2002—$50 or the amount announced through proposed and final rulemaking in connection with ambulatory surgical center services.

(g) HCFA designates a predominant characteristic of a new technology IOL that both sets it apart from other IOLs and links it with other similar IOLs with the same characteristic to establish a specific subset of new technology within the ''class of new technology IOLs.''

(h) Within 90 days of the end of the comment period following the FEDERAL REGISTER notice identified in paragraph (d) of this section, HCFA publishes in the FEDERAL REGISTER its determinations with regard to IOLs that